Remarks

In view of the above amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

Claims 1 and 7 have been amended. Claims 3 and 5 have been cancelled and are now presented in independent form as new claims 22 and 23. No new matter has been introduced by these amendments. Claims 1, 2, 4, and 6-23 are pending.

The specification has been amended to recite the chemical names of saredutant, MEN 10627, talnetant, and osanetant. No new matter has been introduced by these amendments, as indicated by Exhibits 1-4 attached hereto. Exhibit 1 is the U.S. National Library of Medicine record for saredutant; Exhibit 2 is the U.S. National Library of Medicine record for MEN 10627; Exhibit 3 is the U.S. National Library of Medicine record for talnetant; and Exhibit 4 is the U.S. National Library of Medicine record for osanetant. Because the chemical compound name and the systematic name for these materials are synonymous, the introduction of the chemical compound name does not introduce new matter.

The objection to claims 3 and 5 are overcome by the presentation of these claims in independent form (i.e., as claims 22 and 23). This objection should be withdrawn.

The objection to claims 1 and 3 for recitation of the abbreviations NK_2 and NK_3, and for reciting the drug name MEN 10627 is overcome by the above amendments and should be withdrawn.

The rejection of Claims 1, 2, 4, and 6-21 under 35 U.S.C. §112 (first paragraph) as lacking written description support is respectfully traversed.

In the outstanding office action, the U.S. Patent and Trademark Office ('PTO") asserts that the incorporation of essential matter in the specification by reference to an unpublished U.S. application, foreign application, or to a publication is improper. This appears to be in response to applicant's demonstration (in the response filed on February 28, 2007) that a number of U.S. patents, which are incorporated by reference into the specification of the present application, describe how to make hundreds of NK_2 and/or NK_3 (or dual NK_2/NK_3) receptor antagonists falling within different classes of compounds. The PTO position does not make any sense, because all of the evidence that is relied upon by applicant (i.e., in the above-noted response) and incorporated by reference into the specification is from U.S. patents. Because

these cited references that are incorporated by reference are U.S. patents—rather than unpublished U.S. applications, foreign references, or published non-patent literature—the application can legitimately incorporate the contents of these references whether or not the subject matter is essential (applicant submits it is not).

Moreover, even to the extent that any non-patent references that describe prior art NK_2 or NK_3 receptor antagonists are incorporated by reference into the specification, applicant submits that these references do not contain essential matter. The mere fact that the prior art identifies a number of classes of compounds and their activities as NK_2 and/or NK_3 receptor antagonists means that persons of skill in the art were fully aware of the structure/activity relationship for NK_2 and NK_3 receptor antagonists. Because this information already existed in the prior art, there is no need for the present application to present such information. Indeed, the Federal Circuit has confirmed that patent applications need not disclose in detail that which was known in the prior art. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986). Quite the contrary, that which is well known—for the reasons already demonstrated, the structure/activity relationship of various classes of NK_2 and NK_3 receptor antagonists—can be identified without the need of any details about the compounds *per se*.

Recent Federal Circuit decisions concerning the use of known compounds are consistent with this analysis of the law. *See Capon v. Eshhar*, 418 F.3d 1349, 1358, 1360-61, 76 USPQ2d 1078, 1084-85, 1087 (Fed Cir. 2005) (inclusion of known DNA sequences in specification is not required to satisfy written description requirement); *Falkner v. Inglis*, 448 F.3d 1357, 1366, 79 USPQ2d 1001, 1007 (Fed. Cir. 2006) (no *per se* rule that a biological macromolecule of known structure must be recited in the specification to support its use in the claimed invention). Because the subgenera of NK_2 receptor antagonists and NK_3 receptor antagonists possessed *known* structures and *known* activities, there is simply no need for an applicant to include a laundry list of species in the specification. That is not essential matter.

Instead, the detailed information to be identified in the specification is that which is new or not conventional (*see Hybritech*, 802 F.2d at 1384, 231 USPQ at 94), and that is precisely what the present application discloses. The present invention concerns the use of NK_2 and/or NK_3 receptor antagonists for treating hot flashes, i.e., which is a "new use". Consistent with this new use, the present application describes the classes of compounds that can be used to

practice the invention (page 5, line 29 to page 9, line 21), and describes how those compounds can be administered and dosages that can be used to effect the treatment of hot flashes (page 9, line 22 to page 11, line 23). Finally, the specification identifies different types of hot flash patients that can be treated in accordance with the claimed invention (page 11, line 27 to page 12, line 5). From the written description in the present application, persons of skill in the art would appreciate that the applicant was in possession of the claimed invention.

The PTO asserts at page 3 of the outstanding office action that the instant specification fails to indicate that a representative number of structurally related compounds are disclosed, and the skilled artisan would not know the identity of a reasonable number of representative compounds and would not know how to use them.

This position of the PTO is entirely unsupported by the facts and unsupported by the law. As noted above, the structure/activity relationship of hundreds of NK_2 receptor antagonists and NK_3 receptor antagonists were known in the art prior to the present invention. As a consequence, the skilled artisan would already have known what the identity of a reasonable number of representative compounds is and how such compounds can be made and tested for activity as NK_2 receptor antagonists or NK_3 receptor antagonists. Moreover, as noted above, the present application does teach the skilled artisan *how to use* these compounds to treat a patient for hot flashes (e.g., by describing patients to be treated, classes of compounds to be used as well as exemplary compounds, dosages to be used, and routes of administration).

For these reasons, the rejection of claims 1, 2, 4, and 6-21 as lacking written descriptive support is improper and should be withdrawn.

In view of all of the foregoing, applicant submits that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

Date: January 16, 2008

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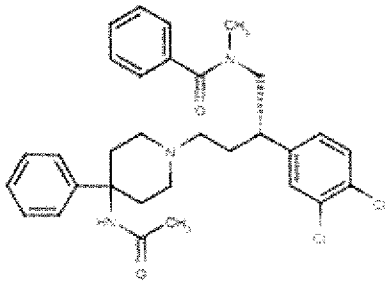
Exhibit 1: U.S. National Library of Medicine record for saredutant

United States National Library of Medicine

ChemIDplus Lite

Full Record

SR 48968
RN: 142001-63-6



Structure Descriptors

InChI
InChI=1/C31H35Cl2N3O2/c1-23(37)34-31(27-11-7-4-8-12-27)16-19-36(20-17-31)18-15-26(25-13-14-28(32)29(33)21-25)22-35(2)30(38)24-9-5-3-6-10-24/h3-14,21,26H,15-20,22H2,1-2H3,(H,34,37)/t26-/m1/s1
Download | View Full InChI

Smiles
C1C(CCN(C1)CC[C@@H](c1cc(c(cc1)Cl)Cl)CN(C)C(c1ccccc1)=O)(c1ccccc1)NC(=O)C
Download

Names and Synonyms

Name of Substance
SR 48968

Synonyms
(S)-N-Methyl-N(4-(4-acetylamino-4-phenylpiperidino)-2-(3,4-dichlorophenyl)butyl)benzamide
N-((S)-beta-(2-(4-Acetamido-4-phenylpiperidino)ethyl)-3,4-dichlorophenethyl)-N-methylbenzamide
SR 48968
SR 48968C
SR-48968
Saredutant

Systematic Name
Benzamide, N-((2S)-4-(4-(acetylamino)-4-phenyl-1-piperidinyl)-2-(3,4-dichlorophenyl)butyl)-N-methyl-
Benzamide, N-(4-(4-(acetylamino)-4-phenyl-1-piperidinyl)-2-(3,4-dichlorophenyl)butyl)-N-methyl-, (S)-

Registry Numbers

CAS Registry Number
142001-63-6

System Generated Number
142001636

Formulas

Molecular Formula
C31-H35-Cl2-N3-O2

Notes

Note
Neurokinin A antagonist; tachykinin receptor antagonist; SR 48965 is the inactive R-enantiomer of SR 48968.

Locators

File Locator

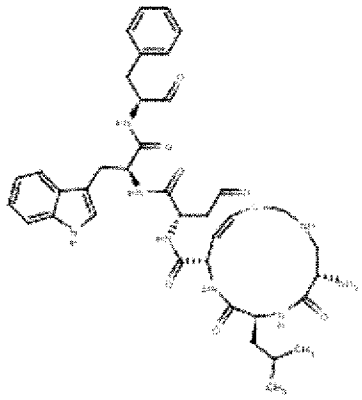
PubMed Cancer	Cancer Citations from PubMed
MeSH	Medical Subject Headings File
TOXLINE	NLM TOXLINE on TOXNET
PubChem	PubChem
USA.gov	USA.gov Search Engine
ClinicalTrials.gov	NIH ClinicalTrials.gov
PubMed	Biomedical Citations From PubMed
PubMed Toxicology	Toxicology Citations From PubMed

Exhibit 2: U.S. National Library of Medicine record for MEN 10627

United States National Library of Medicine | ChemIDplus Lite

Full Record

Men 10627
RN: 157351-81-0



Structure Descriptors

InChI
InChI=1/C38H48N8O7S/c1-23(2)16-32-38(53)44-31(13-15-54-22-40-20-28(39)34(49)45-32)36(51)43-30(12-14-47)35(50)46-33(18-25-19-41-29-11-7-6-10-27(25)29)37(52)42-26(21-48)17-24-8-4-3-5-9-24/h3-11,13-15,19,21,23,26,28,30-33,40-41H,12,16-18,20,22,39H2,1-2H3,(H,42,52)(H,43,51)(H,44,53)(H,45,49)(H,46,50)/b15-13-/t26-,28-,30-,31-,32-,33-/m0/s1
Download | View Full InChI

Smiles
C([C@@H](NC([C@@H](NC([C@@H](NC([C@H]1NC([C@@H](NC([C@@H](N)CNCSC=C1)=O)CC(C)C)=O)=O)CC=O)=O)Cc1c[nH]c2ccccc12)=O)Cc1ccccc1)=O
Download

Names and Synonyms

Name of Substance
Men 10627

Synonyms
Cyclo(met-asp-trp-phe-dap-leu)cyclo(2beta-5beta)
Cyclo(methionyl-aspartyl-tryptophyl-phenylalanyl-diaminopropanoyl-leucyl)cyclo(2beta-5beta)
Men 10,627

Systematic Name
Men 10627

Registry Numbers

CAS Registry Number
157351-81-0

System Generated Number
157351810

Formulas

Molecular Formula
C38-H48-N8-O7-S

Notes

Note
A polycyclic peptide; a tachykinin NK2 receptor antagonist.

Locators

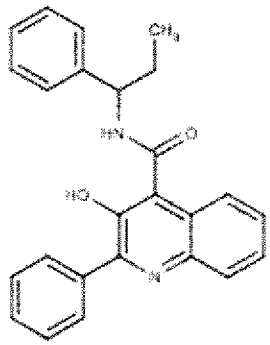
File Locator	
PubMed Cancer	Cancer Citations from PubMed
MeSH	Medical Subject Headings File
PubChem	PubChem
PubMed	Biomedical Citations From PubMed
PubMed Toxicology	Toxicology Citations From PubMed

Exhibit 3: U.S. National Library of Medicine record for talnetant

United States National Library of Medicine | ChemIDplus Lite

Full Record

Talnetant [INN]
RN: 174636-32-9



Structure Descriptors

InChI
InChI=1/C25H22N2O2/c1-2-20(17-11-5-3-6-12-17)27-25(29)22-19-15-9-10-16-21(19)26-23(24(22)28)18-13-7-4-8-14-18/h3-16,20,28H,2H2,1H3,(H,27,29)
Download | View Full InChI

Smiles
n1c(c(c(c2ccccc12)C(=O)N[C@@H](c1ccccc1)CC)O)c1ccccc1
Download

Names and Synonyms

Name of Substance
SB 223412
Talnetant [INN]

Synonyms
N-((S)-alpha-Ethylbenzyl)-3-hydroxy-2-phenylcinchoninamide
N-(alpha-Ethylbenzyl)-3-hydroxy-2-phenylquinoline-4-carboxamide
SB-223412
Talnetant

Systematic Name
4-Quinolinecaeboxamide, 3-hydroxy-2-phenyl-N-((1S)-1-phenylpropyl)-
4-Quinolinecarboxamide, 3-hydroxy-2-phenyl-N-(1-phenylpropyl)-, (S)-

Registry Numbers

CAS Registry Number
174636-32-9

System Generated Number
174636329

Formulas

Molecular Formula
C25-H22-N2-O2

Notes

Note
SB-223412 is the (S)-(-)-isomer.

Locators

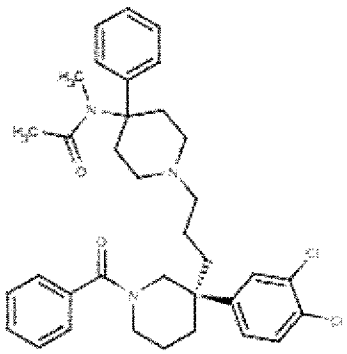
File Locator	
MeSH	Medical Subject Headings File
PubChem	PubChem
USA.gov	USA.gov Search Engine
ClinicalTrials.gov	NIH ClinicalTrials.gov
PubMed	Biomedical Citations From PubMed

Exhibit 4: U.S. National Library of Medicine record for osanetant

United States National Library of Medicine | ChemIDplus Lite

Full Record

Osanetant [INN]
RN: 160492-56-8



Structure Descriptors

Smiles
C(C)(=O)N(C)C1(CCN(CC1)CCC[C@]1(CN(CCC1)C(c1ccccc1)=O)c1cc(c(cc1)Cl)Cl)c1ccccc1
Download

Names and Synonyms

Name of Substance
Osanetant [INN]

Synonyms
N-(1-(3-((R)-1-Benzoyl-3-(3,4-dichlorophenyl)-3-piperidyl)propyl)-4-phenyl-4-piperidyl)-N-methylacetamide
Osanetant

Systematic Name
Acetamide, N-(1-(3-(1-benzoyl-3-(3,4-dichlorophenyl)-3-piperidinyl)propyl)-4-phenyl-4-piperidinyl)-N-methyl-, (R)-
N-(1-(3-((3R)-1-benzoyl-3-(3,4-dichlorophenyl)-3-piperidinyl)propyl)-4-phenyl-4-piperidinyl)-N-methylacetamide

Registry Numbers

CAS Registry Number
160492-56-8

System Generated Number
160492568

Classification Codes

Classification Code
A neurokinin (NK3) receptor antagonist

Formulas

Molecular Formula

C35-H41-Cl2-N3-O2

Locators

File Locator	
PubChem	PubChem
USA.gov	USA.gov Search Engine
PubMed	Biomedical Citations From PubMed
PubMed Toxicology	Toxicology Citations From PubMed